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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/669,596
Filing Date: September 25, 2003
Appellant(s): SCHMIDT, DAVID

Benjamin Esplin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 12, 2009 appealing from the Office action mailed August 19, 2008.

The third party IDS filed 10/24/2008 is not considered as it was not filed within the specified period in CFR 1.99(e) that requires the IDS to be filed within two month of publication of the application under examination. In the instant case the IDS was filed later than two month of publication date of the present application which is 03/25/2004. Further the IDS does not include fees as set forth in CFR 1.17(p).

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct:

Rejection of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, 42, 58 and 59 under 35 U.S.C. 102(e) as being anticipated by US 6,475,514 (Blitzer et al. '514).

Rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of US 5,651,973 (Moo-Young et al. '973).

Rejection of claim 34 under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of 6,558,695 (Luo et al. '695).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,475,514	Blitzer et al.	11-2002
5,651, 973	Moo-Young et al.	07-1997
6,558,695	Luo et al.	05-2003

(9) Grounds of Rejection

The text of the following sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following ground(s) of rejection are applicable to the appealed claims:

(A) Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, 42, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,475,514 (Blitzer et al.).

Blitzer et al. discloses transdermal patches for administration of nutrient supplement to a subject wherein the patch comprises amino acids (abstract; col.2, lines 47-51, 65-67). The amino acids included hydroxyproline that is claimed by applicant by claim 6 as left-handed molecule, further including alanine, valine, phenylalanine, etc. (col.6, lines 65-67; col.7, lines 1-2, 60-67). The patch further includes L-carnitine (col.8, line 8). The patch comprises backing layer, which reads on the claimed substrate, made of polyester fabric (col.9, lines 5-6; col.11, lines 45-59). The patches are stored in pouches comprising polypropylene (col.12, lines 27-37). The patch further comprises adhesive to affix the patch to the skin (col.9, lines 55-57), and the matrix has polymer foam framework, the adhesive layer and polymer foam both read on the enclosure that is adhesive and prevents the organic material from contact subject's body as required by instant claims 1, 58 and 59. The patch comprises additives such as permeation enhancers including glycols, preservatives including alcohols, and plasticizers (col.13, lines 12-15, 49-52; col.14, lines 10-12). The capability of the left-handed molecule of causing beneficial effect as claimed by claim 5 and improving subject stamina as claimed by claim 42 are inherent function of the specific molecule. The limitation "wearable" as claimed by claim 59 is met by the reference because the according to the

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present disclosure, paragraphs 0034 and 0085, applicant defined “wearable object” as “dermal patches”.

(B) Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US ‘514 in view of US 5,651,973 (Moo-Young et al. ‘973).

The teachings of Blitzer are discussed in section 3 as set forth in this office action.

However, US ‘514 does not teach the patch is embodied in a bracelet as claimed by claim 26.

Moo-Young teaches transdermal patch that is attached to the back of suitable article such as wrist band or bracelet in order to eliminate the contact between irritating elements in the patch and the skin (col.11, lines 20-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising plurality of amino acids including hydroxyproline and L-carnitine as disclosed by US ‘514, and attach the patch to a bracelet as disclosed by US ‘973, motivated by the teaching of US ‘973 that when the patch is attached to a bracelet it eliminates skin irritation, with reasonable expectation of having patch comprising amino acids and attached to a bracelet to effectively deliver amino acids to the wearer without irritating the skin.

(C) Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US ‘514 in view of 6,558,695 (Luo et al. ‘695).

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The teachings of US '514 are discussed in section 3 as set forth in this office action.

Although US '514 teaches additives, however, US '514 does not teach the specific additives as claimed by claim 34.

Luo teaches transdermal patch comprising glycerin because it acts as irritation mitigating agent and eliminates the possibility of skin irritation (abstract; col.15, lines 14-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising amino acids including hydroxyproline, L-carnitine, and additives as disclosed by US '514, and replace the additives with glycerin, or further add glycerin to the additives as disclosed by US '695, motivated by the teaching of US '695 that glycerin acts as irritation mitigating agent and eliminates the possibility of skin irritation, with reasonable expectation of having patch comprising amino acids and glycerin to effectively deliver amino acids to the wearer without irritating the skin.

(10) Response to Argument

(A) Claim 1 (and its dependent claims)

Applicant argues that the present claim 1 requires at least one organic material and at least one substrate, wherein said at least one enclosure comprises an adhesive for adhering said at least one enclosure to said subject's body and wherein said at least one enclosure prevents said at least one organic material from direct contact with said

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subject's body while said at least one enclosure is adhered to said subject's body using said adhesive. Blitzer discloses a transdermal patch that delivers nutrients into the blood stream of the body through the epidermis. Blitzer discloses a specific embodiment, shown in FIG. 1 in which an athletic supplement is carried in a polymer matrix 16. The polymer matrix 16 is bounded on one side by a backing layer 12, and on the other side by a pressure sensitive adhesive layer 18 and a release liner 20. In use, liner 20 is removed or dissolved to expose adhesive 18, which secures the polymer matrix 16 to the skin of the user. Adhesive 18 and polymer matrix 16 are configured such that upon application of the patch to the skin of the user, the athletic supplement carried in polymer matrix 16 is released into the skin. In rejecting claim 1, the Examiner alleges that the athletic supplement disclosed in Blitzer can be interpreted as the "at least one organic material" of claim 1, and that polymer matrix 16 and the adhesive 18 can be interpreted as the "at least one enclosure of claim 1." Blitzer discloses that when the adhesive holds the patch in place on a user, the athletic supplement contained within the patch is released into the skin of the user. The athletic supplement thus makes "direct contact" with the skin of the user and passes through it. Therefore, the polymer matrix and adhesive of the patch described in Blitzer do not "prevent said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive."

In response to these arguments, appellant's attention is directed to the fact that it is well established that the claims are given the broadest interpretation during

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prosecution. The scope of the present claim 1 is directed to product (apparatus) comprising specific organic materials, a substrate, and an enclosure so that the organic materials do not directly contact the skin. Regarding the argument that Blitzer teaches transdermal patch, it is noticed that the claims are not directed to "a non-transdermal patch" and the claims do not exclude a transdermal patch. The claims further do not exclude the delivery of the nutrients through the skin. Applicant himself disclosed in paragraphs 0034 and 0085 of the present specification that "wearable objects " include "dermal patches". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.1993). Blitzer teaches product comprising the claimed organic materials and further teaches that matrix, which reads on the substrate, including the organic materials has polymer foam framework (col.18, lines 10-14), and the patch further comprises adhesive to affix the matrix to the skin (col.9, lines 55-57), and both of the foam framework and adhesive layer read on the enclosure that prevents the organic material from direct contact subject's body as required by instant claims 1. The intended use recited by claim 1 including "said enclosure prevents organic material from direct contact with subject body" is met by the reference because the claim requires "prevention of **direct** contact" and not "absolute prevention contact", and the adhesive layer disclosed by Blitzer prevents direct contact of organic materials with the skin. Thus, the enclosure of the organic material as taught by Blitzer prevents **direct** contact. It has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

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order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Therefore, all the elements of claimed product are met by Blitzer, and also the function required by the enclosure is met by the adhesive polymer and foam framework because both of them prevent the matrix comprising the organic materials from **direct** contact with the skin. The present claims do not exclude the release of the supplement from the patch and do not exclude contact with the subject body, only direct contact, and the reference teaches the adhesive layer as well as the foam framework that both prevent the direct contact with the subject's body. Therefore, all the limitation of the claims are met by US '514.

Appellant argues that claims 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42 depend from claim 1 must be overturned due to their dependency on claim 1, as well as for the features that they recite individually.

In response to this argument, it is argued that the rejection of claims 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42 over Blitzer are maintained for the reasons previously stated.

Appellant argues that claim 26 depends from claim 1 and the sections of Moo-Young cited by the Examiner in rejecting claim 26 do not address the deficiencies of Blitzer with respect to claim 1.

In response to this argument, it is argued that all the limitations of claim 1 are met by Blitzer, and Moo-Young is relied upon for the sole teaching of transdermal patch that is attached to the back of suitable article such as wrist band or bracelet in order to eliminate the contact between irritating elements in the patch and the skin.

Appellant argues that claim 34 depends from claim 1, and the sections of Luo cited by the Examiner in rejecting claim 34 do not address the deficiencies of Blitzer with respect to claim 1.

In response to this argument, it is argued that all the limitations of claim 1 are met by Blitzer, and Luo is relied upon for the sole teaching of transdermal patch comprising glycerin that acts as irritation mitigating agent and eliminates the possibility of skin irritation.

Additionally, regarding Moo-Young and Luo references, it has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." At the time of the invention patch comprising plurality of amino acids including hydroxyproline

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and L-carnitine was known and disclosed by Blitzer, and also transdermal patch attached to wrist band or bracelet were known and disclosed by Moo-Young to be beneficial to eliminate the contact between irritating elements in the patch and the skin. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the patch of Blitzer attached to wrist band or bracelet of Moo-Young, with reasonable expectation of having patch comprising amino acids and attached to a bracelet to effectively deliver amino acids to the wearer without irritating the skin.

Further, at the time of the invention it was known at the art to include glycerin into transdermal patch because glycerin acts as irritation mitigating agent and eliminates the possibility of skin irritation as disclosed by Luo et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to add glycerin to the transdermal patch disclosed by Blitzer, motivated by the teaching of Luo that glycerin acts as irritation mitigating agent and eliminates the possibility of skin irritation, with reasonable expectation of having patch comprising amino acids and glycerin to effectively deliver amino acids to the wearer without irritating the skin.

(B) Claim 58

Appellant hereby repeats the argument regarding Blitzer reference, and further argues that claim 58 further requires that the at least one organic material and substrate are enclosed in said at least one enclosure.

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In response to this argument, it is argued that Blitzer disclosed the same organic materials in a matrix that reads on a substrate, and further teaches the adhesive layer and the foam framework and the backing that forms enclosure that encloses the matrix comprising the organic material which reads on the organic material and substrate. Blitzer meets the limitation of claim 58. The intended use recited by claim 58 including "said enclosure prevents organic material from direct contact with subject body" is met by the reference because the claim requires "prevention of **direct** contact" and not "absolute prevention contact", and the adhesive layer disclosed by Blitzer prevents direct contact of organic materials with the skin. Thus, the enclosure of the organic material as taught by Blitzer prevents **direct** contact.

(C) Claim 59

Appellant hereby repeats the argument regarding Blitzer reference, and further argues that claim 59 further requires that the at least one wearable object is worn on said subject's body.

In response to this argument, it is argued that Blitzer teaches that the patch (apparatus) is worn on the skin. Blitzer meets the limitation of claim 59.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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